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APPLICATION NO	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO	CONFIRMATION NO
09/673,174	10/12/2000	Hilary Koprowski	JEFF-KOPOI.P	2234

7590

10/21/2002

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EXAMINER

BROWN, STACY S

ART UNIT

PAPER NUMBER

1648

DATE MAILED: 10/21/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/673,174

Applicant(s)

KOPROWSKI ET AL.

Examiner

Stacy S Brown

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 September 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) 5-16 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 13 September 2002 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other

DETAILED ACTION

1. Applicant's amendment dated September 4, 2002 is acknowledged and entered. Claims 1-16 are pending. Claims 5-16 are withdrawn from consideration, being drawn to non-elected inventions. Claims 1-4 are examined.

Response to Amendment

2. The rejection of claim 3 under 35 U.S.C. 112, second paragraph, is withdrawn in view of Applicant's amendment. The rejection of claims 1-4 under 35 U.S.C. 103(a) as obvious over Goodman in view of Ma and Lomonosoff is withdrawn in view of Applicant's persuasive arguments. However, new grounds of rejection are made in this Office Action. Therefore, this action is non-final.

Claim Rejections - 35 USC § 103

3. Claims 1-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Donson *et al* (5,316,931) in view of Ma *et al* (of record), Goodman *et al* (of record) and Donson *et al* (*PNAS USA*, 1991). The claims are drawn to a method for producing a full-length antibody in a host plant (dicotyledon or monocotyledon) using a virus comprising 1) constructing a first recombinant viral vector encoding heavy chain, 2) constructing a second recombinant viral vector encoding light chain, 3) infecting the host plant with both recombinant vectors to result in systemic infection and 4) expressing heavy and light chains in assembled form into full-length antibodies. The full-length antibody can be monoclonal, and can be directed against several disease-related antigens.

Donson ('931) teaches a method for systemically expressing foreign genes in plants via plant viral vectors. The recombinant viral vectors comprise a promoter, coat protein coding sequence, and a non-native sequence for expression (abstract). The foreign sequence can be an antibody (col. 14, line 66).

Donson ('931) fails to teach the production of a monoclonal antibody by introducing separate vectors that will express light and heavy chains. Donson fails to teach the antigens that the antibodies bind.

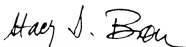
However, Ma teaches the assembly of monoclonal antibodies in transgenic plants. With regard to the light and heavy chains, and various antigens, Goodman's teachings are of record. Although Ma's system and Goodman's system teaches the use of transgenic plants, it would have been obvious to use the system of Donson (931') instead of transgenics. One would have been motivated to use Donson's viral vectors instead of transgenics, as taught by Donson (1991). Donson (1991) teaches that viral vectors are simpler and less time-consuming than transgenics (page 7204, col. 1, first paragraph). Further, Donson (931') teaches that viral vectors are advantageous over transgenics because they do not require transformation and are stable (col. 8, lines 13-26). One would have had a reasonable expectation of success that the antibodies of Ma would be assembled using the method of Donson because Donson suggests the production of antibodies (col. 14, line 66). Therefore, the invention as a whole would have been obvious at the time the invention was made.

Conclusion

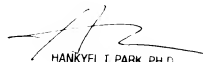
4. No claim is allowed.

Papers relating to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 located in Crystal Mall 1. The Fax number for Art Unit 1648 is (703) 308-4426. All Group 1600 Fax machines will be available to receive transmissions 24 hrs/day, 7 days/wk. Please note that the faxing of such papers must conform with the Notice published in the Official Gazette, 1096 OG 30, (November 15, 1989).

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Stacy S. Brown, whose telephone number is (703) 308-2361. The Examiner can normally be reached on Monday through Friday and alternate Wednesdays from 6:30 AM-4:00 PM, (EST). If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, James C. Housel, can be reached at (703) 308-4027. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.



Stacy S. Brown
October 12, 2002



HANKYEL T. PARK, PH.D.
PRIMARY EXAMINER